

The opinion in support of the decision being entered today was **not** written for publication and is **not** binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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Ex parte JOSEPH J. KIRCHER, RONALD W. CZARNY, ROBERT E. LEWIS,  
DIAN M. NITZKI-GEORGE and JOE A. MILLER

Appeal No. 2004-2032  
Application No. 09/729,498

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ON BRIEF

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Before GARRIS, WARREN, and PAWLIKOWSKI, Administrative Patent Judges.

GARRIS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on an appeal from the Examiner's rejection of claims 1-31 which are all of the claims pending in the above identified application. On page 2 of the answer, the Examiner has stated that the rejection of claims 6-8, 12, 13, 19-21, 23, 28 and 29 has been dropped. As a consequence, the only claims remaining before us on this appeal are claims 1-5, 9-11, 14-18, 22, 24-27, 30 and 31.

The subject matter on appeal relates to an apparatus and to a method for controlling the operation of a pharmaceutical compounder which respectively comprises a computing means and step for

determining the compatibility of the pharmaceutical components relative to one another and determining the order in which the components are transferred in preparing a prescription admixture. Further details of this appealed subject matter are set forth in representative independent claims 1 and 24<sup>1</sup> which read as follows.

1. Apparatus for use in controlling the operation of at least one pharmaceutical compounder adapted to selectively transfer prescribed amounts of pharmaceutical components from individual source containers through elongated hollow transfer means to a final container in order to prepare a prescription admixture, said apparatus comprising:

computing means having memory means for storing instructions for operating the apparatus and for controlling the compounders to prepare a prescribed admixture, said memory means including data relating to a plurality of the pharmaceutical components that may be transferred to prepare the prescription admixture, and data concerning the operating characteristics of at least one of the compounders that the apparatus is adapted to control;

said computing means including at least one communication port for establishing a communication link with each compounder that is to be controlled;

said computing means being adapted to receive a prescription admixture, identify the pharmaceutical components thereof, determine the compatibility of the pharmaceutical components relative to one another, determine the order in which the components are transferred in preparing the prescription admixture, and communicate the instructions for preparing the prescription admixture to the compounders that are to be used in preparing the prescription admixture.

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<sup>1</sup> We note the following informality in claim 24 which is deserving of correction. With reference to the claim 24 copy which appears in the brief appendix, the phrase "the apparatus" on line 5 lacks strict antecedent basis. This informality would be rectified by, for example, inserting the phrase --an apparatus including-- after the recitation "controlling the operation of" on line 1.

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24. A method of controlling the operation of at least one pharmaceutical compounder adapted to selectively transfer prescribed amounts of pharmaceutical components from individual source containers through elongated hollow transfer means to a final container in order to prepare a prescription admixture, the method utilizing a computing means having memory means for storing instructions for operating the apparatus and for controlling the compounders to prepare a prescribed admixture, with the memory means including data relating to a plurality of the pharmaceutical components that may be transferred to prepare the prescription admixture, and data concerning the operating characteristics of at least one of the compounders that the apparatus is adapted to control, the computing means including at least one communication port for establishing a communication link with each compounder that is to be controlled, the method comprising the steps of:

receiving a prescription admixture in the computing means;

identifying and determining the amounts of the pharmaceutical components of the prescription admixture;

determining the compatibility of the pharmaceutical components relative to one another;

determining the order in which the components are transferred during the preparation of the prescription admixture; and,

communicating the instructions for preparing the prescription admixture to the at least one compounder that is to be used in preparing the prescription admixture.

The references relied upon by the Examiner as evidence of obviousness are:

Lewis et al. (Lewis)                      5,228,485                      Jul. 20, 1993

Baxter "Multitask Operating System for Automix® Compounders Version 2.30" Operator's Manual, May 1999

Claims 1-4, 10 and 24-27 are rejected under 35 U.S.C. § 102(b) as being anticipated by Lewis.

Claims 5, 9, 11, 14-18, 22, 30 and 31 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lewis in view of Baxter.

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We refer to the brief and reply brief and to the answer for a complete exposition of the opposing viewpoints expressed by the Appellants and by the Examiner concerning the above noted rejections.

#### OPINION

For the reasons which follow, these rejections cannot be sustained.

As a preliminary matter, it is appropriate to express our construction of the independent claims on appeal. We begin doing so by observing that, during examination proceedings, claims are given their broadest reasonable interpretation consistent with the specification. In re Hyatt, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000). Thus, it is reasonable to interpret independent apparatus claim 1 and independent method claim 24, consistent with the subject specification, as being limited to a computer means which performs the claim 1 functions and the claim 24 steps of determining the compatibility of the pharmaceutical components relative to one another and determining the order in which the components are transferred during the preparation of the prescription admixture. This claim construction corresponds to that expressed by both the Appellants and the Examiner on the record of this appeal.

Concerning the § 102 rejection, it is well settled that anticipation is established only when a single prior art reference discloses, expressly or under principles of inherency, each and

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every element of the claimed invention. RCA Corp. V. Applied Digital Data Sys., Inc., 730 F.2d 1440, 1444, 221 USPQ 385, 388 (Fed. Cir. 1984). A finding of anticipation establishes that all aspects of the claimed invention were already described (expressly or inherently) in a single prior art reference, and such a finding is not supportable if it is necessary to prove facts beyond those disclosed in the reference in order to meet the claim limitations. Scripps Clinic & Research Found. v. Genentech Inc., 927 F.2d 1565, 1576, 18 USPQ2d 1001, 1010 (Fed. Cir. 1991). Therefore, it is also well settled that anticipation cannot be predicated on mere conjecture. W.L. Gore & Assocs. v. Garlock, Inc., 721 F.2d 1540, 1554, 220 USPQ 303, 314 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984).

It is the Examiner's anticipation viewpoint that the aforementioned computing means requirements of independent claims 1 and 24 are satisfied by the control means of Lewis. In this regard, the Examiner cites the control means disclosure at lines 44-53 in column 6 of Lewis as support for his finding that "the control means does have the ability of determining if the components are compatible and altering the order of dispensing when properly programmed" (answer, page 12). We cannot agree with the Examiner that his finding is supported by the Lewis disclosure generally including the column 6 disclosure specifically.

In column 6, Lewis teaches that:

"[t]he control means may allow a second fluid to flow into the chamber when a first fluid is still present in the chamber if the first and second fluids are compatible... [but]

will not allow a second fluid to enter the chamber when a first fluid is still present if the two fluids are incompatible with each other, when properly programmed..." [lines 44-52].

We do not find in this or any other disclosure of the Lewis patent any teaching that it is patentee's control means itself which determines the compatibility versus incompatibility of the fluids. On the contrary, the aforequoted recitation "when properly programmed" (column 6, line 52) clearly indicates that it is the programmer/operator of Lewis' apparatus who performs the function and step of determining whether fluids are compatible or incompatible with one another. Furthermore, this indication is reinforced by patentee's teaching at line 64 in column 30 through line 7 in column 32 wherein patentee teaches that normally a rinse will not be conducted unless the next fluid to be pumped is incompatible with the previous fluid (see lines 6-10 in column 31) and that an operator of the device may indicate that a rinse is required when information is being entered into the device (see lines 62-64 in column 31).

In light of the foregoing, it is reasonably apparent that, in Lewis's invention, the function and step of determining whether fluids are compatible with one another are not performed by patentee's control means as the Examiner believes but instead are performed by an operator when programming the control means. The Examiner may consider the so-programmed control means to perform the determining function and step under consideration. This is incorrect. While the control means effectuates the function

programmed by the operator, such effectuation constitutes nothing more than the initiation of pre-programmed events. This event initiation by Lewis' control means is based solely on operator programming and thus does not include the function or step of compatibility determination. For this reason, patentee's control means is plainly distinct from the Appellants' claimed computing means which performs the function and step of determining the compatibility of pharmaceutical components relative to one another.

The circumstances recounted above persuade us that the Examiner's anticipation finding is erroneous for a number of reasons. First, as correctly indicated by the Appellants, the Examiner has improperly focused on the column 6 disclosure of Lewis without regard to context with the entire disclosure as a whole. By doing so, the Examiner seemingly has failed to appreciate that, in Lewis' invention, the compatibility versus incompatibility of fluids is determined by the operator when programming the control means rather than by the control means itself. Second, in considering patentee's column 6 disclosure, the Examiner in essence has assumed that fluid compatibility versus incompatibility was determined by the control means even though the disclosure contains no express teaching of such determination as we pointed out earlier. In this regard, we reiterate the previously mentioned legal principle that anticipation cannot be predicated on conjecture. W.L. Gore & Assocs. v. Garlock, Inc., 721 F.2d at 1554, 220 USPQ at 314. Stated otherwise, under § 102, a reference

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must clearly and unequivocally disclose the claimed invention or direct those skilled in the art thereto. In re Arkley, 455 F.2d 586, 587, 172 USPQ 524, 526 (CCPA 1972). Here, no portion including column 6 of the Lewis patent clearly and unequivocally discloses the compatibility determining function and step claimed by the Appellants. Finally, it appears the Examiner erroneously considers the programmed control means of Lewis to perform this claimed determining function and step.

In view of these aforementioned errors by the Examiner, we cannot sustain his § 102 rejection of claims 1-4, 10 and 24-27 as being anticipated by Lewis. As for the § 103 rejection, the additional reference to Baxter, as applied and relied upon by the Examiner, does not supply the deficiencies of Lewis. It follows that we also cannot sustain the § 103 rejection of claims 5, 9, 11, 14-18, 22, 30 and 31 as being unpatentable over Lewis in view of Baxter.




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The decision of the Examiner is reversed.

REVERSED

BRADLEY R. GARRIS  
Administrative Patent Judge

  
CHARLES F. WARREN  
Administrative Patent Judge

BOARD OF PATENT  
APPEALS  
AND  
INTERFERENCES

BEVERLY A. PAWLIKOWSKI  
Administrative Patent Judge

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